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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,138	11/28/2001	Forrest C.M. Pape	P-9682.00	3071

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EXAMINER

MACHUGA, JOSEPH S

ART UNIT PAPER NUMBER

3762

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/996,138	Applicant(s) PAPE ET AL. CH	
	Examiner Joseph S. Machuga	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41 is/are allowed.
- 6) ☒ Claim(s) 1-15, 19-35, 39, 40 and 42-57 is/are rejected.
- 7) ☒ Claim(s) 16-18 and 36-38 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is indefinite and confusing. The claim recites "means for implanting" rather than the generator and sensor itself making the resulting claim indefinite since the structure components necessary to produce and sense the magnetic field required later in the claim are missing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 43 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by
Mueller #5161540.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8-10, 12-15, 21-24, 28-30, 32-35, 43-46, 48, 50, 51-53, 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemmingsson #6421565 in view of Mueller #5161540 and Bornzin et al #5549650.

Hemmingsson discloses a cardiac monitoring device. The device includes a sensing system (1,2) implanted within the heart. The system determines the distance between the heart walls to calculate the cardiac performance. The information may then be used to control the pacing of the heart (column 3, lines 20+.) Not disclosed by this reference is the use of a magnet to sense the distance and the step of determining the change in magnitude of the signal.

Mueller discloses an implantable heart sensor that includes a permanent magnet and a Hall effect sensor to determine distance in a heart chamber.

Bornzin et al teaches using the cardiac wall displacement, velocity and acceleration to determine cardiac performance. This information can also be used in a closed feedback loop to adjust the timing of the pacemaker.

Given these teachings it would have been obvious to one of ordinary skill in the art to use a magnet and a Hall effect sensor to determine the distance within a heart chamber in place of the ultrasound probe in Hemmingsson's device given that it's a simple, low power alternative to the ultrasound system. To use the displacement, velocity and acceleration to calculate the performance of the heart would have been obvious given Bornzin et al's teaching that the performance can be calculated from this. To further use this data to control pacing as defined in the claims would have been obvious given Bornzin et al's teaching that a closed loop system is desirable.

Claims 5-7, 25-27, 47 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemmingsson #6421565 in view of Mueller #5161540 and Bornzin et al #5549650 as applied to claims 1-4, 8-10, 12-15, 21-24, 28-30, 32-35, 43-46, 48, 50, 51-53, 55 and 57 above, and further in view of White et al #5458621.

White et al teach that it is old and well known to locate a component of a pacemaker, such as a sensor, within the coronary vein. This location is well known to be safer than within the left ventricle itself. Given this disclosure it would have been obvious to one of

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ordinary skill in the art to locate the magnet of the proposed combination within the coronary vein to reduce the risks associated with such an implant.

Claims 11, 31 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemmingsson #6421565 in view of Mueller #5161540 and Bornzin et al #5549650 as applied to claims 1-4, 8-10, 12-15, 21-24, 28-30, 32-35, 43-46, 48, 50, 51-53, 55 and 57 above, and further in view of Jirak #3949758.

Jirak discloses a pacemaker having means to adjust the energy output based on whether capture occurred. The design would reduce the drain on the battery of the implant. Given this teaching it would have been obvious to one of ordinary skill in the art to adjust the energy output in the pacemaker of the proposed combination to optimize the system and reduce the drain on the battery.

Claims 19, 20, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemmingsson #6421565 in view of Mueller #5161540 and Bornzin et al #5549650 as applied to claims 1-4, 8-10, 12-15, 21-24, 28-30, 32-35, 43-46, 48, 50, 51-53, 55 and 57 above, and further in view of Fain et al #5730141.

Fain et al discloses a pacemaker having a sensing system the monitors the heart chamber. The device looks for irregular intervals and from this data decides whether tachyarrhythmia is present. Given this teaching, it would have been obvious to one of

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ordinary skill in the art to take the output signal from the sensor of the proposed combination and use it to determine whether tachyarrhythmia is presents based on irregularities such as timing, force, volume, etc.

Claims 16-18 and 36-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

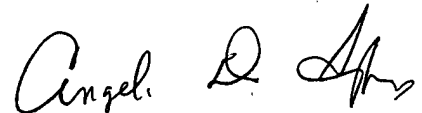
Claim 41 is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on M-F 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
